

## REMARKS

In the September 25, 2002 Office Action, the Examiner rejected claims 1-8 pending in the application. In addition, the Examiner objected to the specification for various reasons. This response cancels claims 2, 6 and 8, without prejudice or disclaimer and amends claims 1, 3-5 and 7 for consideration. After entry of the foregoing amendments, claims 1, 3-5 and 7 (1 independent claim; 4 dependent claims) remain pending in the application. Reconsideration is respectfully requested.

The Examiner first objected to the specification due to various informalities outlined on pages 2-3 of the Examiner's Office Action. In response to the Examiner's objections, Applicants have amended the specification as indicated above to address the informalities pointed out by the Examiner. Claims 2 and 5-8 stand rejected under 35 U.S.C. §112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed. More specifically, the Examiner contends that there is no support in the specification for the recitation in the claims which reads "affinity reagent is bound to a filter element". In that Applicants have amended their claimed invention to more clearly point out and distinctly claim the invention, this rejection is now believed to be moot.

### 35 U.S.C. §102 Rejections

Claim 1 stands rejected under 35 U.S.C. §102(b) as being anticipated by Rosman et al, U.S. Patent No. 5,079,170 issued January 7, 1992 (hereinafter "Rosman"). In particular, the Examiner states that Rosman discloses a tip comprising a filter matrix and an immunologically active substance (affinity reagent) such as antibodies or antigens. Applicants respectfully traverse this rejection.

Rosman generally discloses a sample applicator used in performing immunoassays which includes a tube having an internal lumen and a filter matrix located at one end of the tube. Rosman further discloses that it may be desirable to coat the inside surface of the applicator tube, and particularly the portion located above the filter matrix, with an immunologically active substance such as an antibody, antigen or the like. (See column 6, lines 10-15). This disclosure is in contrast to Applicants' claimed invention where an antibody or antigen is immobilized to a

solid substrate for binding to a component of a specimen and the affinity reagent bound to the component is then retained within a filter contained in a pipette tip. In Rosman, the antibody or antigen is not retained within the filter matrix. Accordingly, in that each of the limitations in Applicants' claim is not disclosed by Rosman, Rosman cannot anticipate Applicants' claimed invention.

Claims 1 and 3 stand rejected under 35 U.S.C. §102(b) as being anticipated by Wainwright et al, U.S. Patent No. 5,171,537, issued December 15, 1992 (hereinafter "Wainwright"). More specifically, the Examiner states that Wainwright discloses a micropipette tip having an affinity reagent present within the tip. Applicants respectfully traverse this rejection.

Wainwright discloses a tip having at least two axially spaced projections formed on the wall of its axial bore that extend radially and part way into the bore to define a reaction chamber in the tip of the bore. A spherical receptor element is mounted in the reaction chamber and is coated with a ligand having a specific affinity for a target molecule in the sample. Unlike Applicants' currently claimed invention, Wainwright fails to disclose an antigen or antibody bound to a target molecule which is retained in a filter element contained in the pipette tip. Therefore, in that Wainwright fails to disclose a filter element, as required by Applicants' claims, Wainwright cannot anticipate Applicants' currently claimed invention.

Claims 1-5, 7 and 8 stand rejected under 35 U.S.C. §102(e) as being anticipated by Raybuck et al, U.S. Patent No. 5,833,927, issued November 10, 1998 (hereinafter "Raybuck"). In particular, the Examiner states that Raybuck discloses a pipette tip having an open rearward end adapted to be fitted on a micropipette for drawing fluid into the pipette tip. The Examiner further states that Raybuck discloses a porous membrane (or filter element) mounted at or adjacent the forward end of the micropipette tip which may be secured to the forward end of the pipette tip by means of a securing collar. The Examiner also states that Raybuck discloses that the membrane may be made peelable from the pipette tip for subsequent processing and that an antibody or other specific binding species can be immobilized on the membrane by a variety of chemical and physical means. Applicants respectfully traverse this rejection.

Raybuck discloses a membrane (17) adapted to fit across the end of a pipette tip. (See Fig. 1). Raybuck further discloses that the membrane can be made of any material that can be activated chemically or physically in a way that it binds the component to be captured such as by

use of an antibody or other specific binding species. However, despite whether the porous membrane functions as a filter element or a solid substrate to which an antibody or other specific binding species binds, Raybuck still fails to disclose an additional limitation required by Applicants' claims, namely an additional filter element which retains the antibody or specific binding species containing porous membrane or an additional solid substrate bound to an antibody or specific binding species which is then retained by the porous membrane. Accordingly, in that Raybuck fails to disclose each and every element of Applicants' claimed invention, Raybuck cannot anticipate Applicants' claimed invention.

Claims 1 and 3 stand rejected under 35 U.S.C. §102(a) as being anticipated by Beiber et al, (Mass Spectrometric Immunoassay, Anal. Chem. 1995, 67, 1153-1158) (hereinafter "Beiber"). In particular, the Examiner states that Beiber discloses a filter pipette tip having an affinity reagent present within the tip. Applicants respectfully traverse this rejection.

Under 35 U.S.C. §102(a) a person is entitled to a patent unless the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the Applicant for a patent. The Beiber journal article cited by the Examiner does not constitute a description of the invention in a printed publication before the invention was made by Applicants in that Applicants are the authors of the journal article, and Applicants conceived their invention before the publication of their journal article. Accordingly, claims 1 and 3 are not anticipated by Beiber and Applicants respectfully request the withdrawal of the Examiner's rejection under 35 U.S.C. §102(a) based on Beiber.

### **35 U.S.C. §103 Rejections**

Claims 2, 4 and 5 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Beiber in view of Raybuck. In particular, the Examiner states that Beiber discloses the instant invention except for the fact that the affinity reagent is bound to a filter element. The Examiner further contends that Raybuck discloses a micropipette tip having a porous membrane element which has specific binding partners bound to the surface for capturing the corresponding analyte. The Examiner therefore contends that it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the bound affinity reagent taught by Raybuck into the device of Beiber because Raybuck shows that this provides for a device for capturing a component present in a fluid and further provides the advantage of capturing the

desired component on or at or in the forward-facing surface of the membrane to allow for easy access for subsequent treatment. Applicants respectfully traverse this rejection.

As previously pointed out above with reference to the Examiner's 35 U.S.C. §102(a) rejection based on Beiber, the Beiber reference does not constitute prior art for purposes of the Examiner's 35 U.S.C. §103(a) rejection because the Beiber publication was authored by the inventors and the inventors conceived of the invention prior to the publication. Accordingly, if the Beiber reference is removed from the Examiner's 35 U.S.C. §103(a) rejection, it would clearly not have been obvious to one of ordinary skill in the art to arrive at Applicants' currently claimed invention. Furthermore, as previously pointed out with respect to the Examiner's 35 U.S.C. §102(e) rejection based on Raybuck, Raybuck fails to disclose each of the limitations of Applicants' currently claimed invention. Accordingly, it could not have been obvious to one of ordinary skill in the art to arrive at Applicants' currently claimed invention if given the Raybuck reference. Therefore, Applicants respectfully request the withdrawal of the Examiner's 35 U.S.C. §103(a) rejection.

In view of the foregoing, Applicants respectfully submit that all of the pending claims fully comply with 35 U.S.C. §112 and are allowable over the prior art of record. Reconsideration of the application and allowance of all pending claims is earnestly solicited. Should the Examiner wish to discuss any of the above in greater detail or deem that further amendments should be made to improve the form of the claims, then the Examiner is invited to telephone the undersigned at the Examiner's convenience.

Respectfully submitted,

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